Adoption Certification Workgroup

Working Document

April 30, 2010 Conference Call

III. Provisions of Permanent Process Section D.1.c. Page 11349

Elements of Surveillance

….., we recognize that it would likely benefit the HIT industry if certain common elements of surveillance could be developed and we welcome public comment on what those elements should be.

De-Certification

Section II.D. 1. c Page 11349 and 11350

We request public comment on whether the National Coordinator should consider proactively stepping-in to protect purchasers of Complete EHRs and/or EHRs Modules by taking action such as ‘‘de-certifying’’ Complete EHRs and/or EHR Modules if a pattern of unsatisfactory surveillance results emerges and the ONC–ACB has not taken any measures to evaluate the poor performance.

Section III.E. 8. **Differential Certification** Page 11351

We expect that over time the certification criteria adopted by the Secretary will increase incrementally, much like the approach CMS has proposed for meaningful use objectives and measures. As a result, after Complete EHRs and EHR Modules have been certified to meet the certification criteria associated with meaningful use Stage 1, it may benefit both Complete EHR and EHR Module developers as well as eligible professionals and eligible hospitals if some form of differential certification were available. Differential certification would comprise an ONC–ACB certifying Complete EHRs and/or EHR Modules to the differences between the certification criteria adopted by the Secretary associated with one stage of meaningful use and a subsequent stage of meaningful use. For example, if the Secretary were to adopt 5 new certification criteria to support meaningful use Stage 2 and those were the only additional capabilities that needed to be certified in order for a Complete EHR’s certification to be valid again (*i.e.,* all other certification criteria remained the same) for the purposes of meaningful use Stage 2, then the Complete EHR would only have to be tested and certified to those 5 criteria rather than the entire set of certification criteria again. We request public comment on factors that could be considered to determine when differential certification would be appropriate and when it would not. Factors we have considered include, whether the standard(s)

associated with a certification criterion or certification criteria change and whether additional certification criteria change in such a way that the new capabilities a Complete EHR or EHR Module would need to provide impact how other previously certified capabilities would perform. We believe that differential certification could be a valuable and pragmatic approach for the future and that it may further reduce costs for certification and expedite the certification process. We request public comment on whether we should require ONC–ACBs to offer differential certification. In considering this request, we also ask when differential certification should begin. That is, should differential certification be permitted to begin with Complete EHRs and EHR Modules certified under the temporary certification program (*i.e.,* the differences between 2011 and 2013) or after all Complete EHRs and EHR Modules have been certified once under the permanent certification program (*i.e.,* the differences between 2013 and 2015). We ask commenters to consider this distinction because of the differences in rigor that we expect Complete EHRs and EHR Modules will go through to get certified under the permanent certification program.

Section III.F.2 Page 11352

AA Ongoing Responsibilities

In order to ensure that our programmatic objectives for the permanent certification program are met, we propose that an ONC–AA would fulfill, at a minimum, the following ongoing responsibilities:

- Maintain conformance with ISO 17011;
- In accrediting certification bodies, verify conformance to, at a minimum, Guide 65;
- Verify that ONC–ACBs are performing surveillance in accordance with their respective annual plans; and
- Review ONC–ACB surveillance results to determine if the results indicate any substantive nonconformance with the terms set by the ONC–AA when it granted the ONC–ACB accreditation.

We request public comment on these and potentially other ongoing responsibilities that we should expressly require an ONC–AA to fulfill.

3. Number of ONC–AAs and Length of Approval

We believe that it is important for all applicants for ONC–ACB status to be accredited by the same ONC–AA. Doing so would provide stability and consistency for all ONC–ACB applicants and a common point of trust for Complete EHR and EHR Module developers. Moreover, Complete EHR and EHR Module developers would obtain a level of assurance that any ONC–ACBs' certification would be equal to another's because all of them had been accredited by the same ONC–AA. As a result, we believe that it is

important from a programmatic perspective for there to be only one ONC–AA at a time and therefore we have proposed to only approve one ONC–AA at a time. We request public comment on whether it would be in the best interest of the ONC–ACB applicants and Complete EHR and EHR Module developers to allow for more than one ONC–AA at a time. Finally, we propose that ONC–AA status would expire after 3 years. Consistent with this proposed expiration of status, we propose to again accept requests for ONC–AA status 120 days before the then current ONC–AA's status is set to expire. We believe that 3 years provides an appropriate balance between precluding other qualified accreditation organizations from requesting ONC–AA status and providing some level of consistency between the ONC–AA and ONC–ACB levels. We request public comment on whether we should extend the length of an ONC–AA's status to a maximum of 5 years before accepting requests for ONC–AA status or shortening the length to 2 years or identify a different period of time.

G. Promoting Participation in the Permanent Certification Program

In the context of the permanent certification program, it is our hope and expectation that multiple organizations will step forward to apply for and receive ONC–ACB status and that these organizations will be able to certify Complete EHRs and EHR Modules in a timely and satisfactory manner. Moreover, given the proposed Medicare and Medicaid EHR Incentive Programs, we believe that organizations will be motivated to become ONC–ACBs to meet the demand for Certified EHR Technology by eligible professionals and eligible hospitals. We do not believe that the requirements set forth in this proposed rule create prohibitively high barriers to market entry for organizations interested in becoming ONC–ACBs. However, we welcome comments on whether this proposed rule does in fact create high barriers to market entry and, if so, how we could revise the proposed requirements to lower those barriers and encourage participation

I Background

Section I.B.2.d., Page 11332

Stark Exception

We request comment on whether we should construe the proposed new ''authorization'' process as the Secretary's method for ''recognizing'' certification bodies in the context of the physician self-referral EHR exception and anti-kickback EHR safe harbor.

Dual Accreditation

Section I.F.2 Page 11336
However, in order for a single organization (which may comprise subsidiaries or components) to perform both testing and certification under the permanent certification program it would need to be: (1) Accredited by an ONC–AA and subsequently become an ONC–ACB; and (2) accredited by the NVLAP.
We request public comment on whether we should give organizations who are ''dual accredited'' and also become an ONC–ACB a special designation to indicate to the

public that such an organization would be capable of performing both testing and certification under the permanent certification program.

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3. Authorization To Certify Other HIT

Do we want to comment on whether other HIT systems should be certified? (e.g. PHR systems).